



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/230,048	03/12/1999	BERNHARD FLECKENSTEIN	058315/0129	4939

26633 7590 11/27/2002

HELLER EHRMAN WHITE & MCAULIFFE LLP
1666 K STREET,NW
SUITE 300
WASHINGTON, DC 20006

EXAMINER

KAUSHAL, SUMESH

ART UNIT PAPER NUMBER

1636

DATE MAILED: 11/27/2002

96

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/230,048

Applicant(s)

FLECKENSTEIN ET AL.

Examiner

Sumesh Kaushal Ph.D.

Art Unit

1636

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 September 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 13-17, 29-33 and 36-53 is/are pending in the application.
- 4a) Of the above claim(s) 13-15, 17 and 29-33 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 36-39, 43, 45, 47-49, 52 and 53 is/are allowed.
- 6) ☒ Claim(s) 42, 46, 50 and 51 is/are rejected.
- 7) ☐ Claim(s) 40, 41 and 44 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____. 6) ☐ Other: _____

DETAILED ACTION

Applicant's response filed on 09/19/02 has been acknowledged.

Claims 40 and 50 were amended.

Claims 13-17, 29-33 and 36-53 were pending.

Claims 36-53 were examined in this office action.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The references cited herein are of record in a prior Office action.

This application contains claims 13-15, 17 and 29-33 drawn to an invention non-elected with traverse in Paper No: 6. A complete reply to the final rejection must include cancellation of non-elected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

► *If the claims are amended, added and/or canceled in response to this office action the applicants are required to follow Amendment Practice under 37 CFR § 1.121 (<http://www.uspto.gov>) and A CLEAN COPY OF ALL PENDING CLAIMS IS REQUESTED.*

Claim Rejections - 35 USC § 102

Claims 46, 50 and 51 are rejected under 35 U.S.C. 102(e) as being anticipated by Ganem et al (US 5,861,240, 1999, filed 02/28/1996, *ref of record*) for the same reasons of record as set forth in the office action mailed on 07/02/02.

The applicant argues that the cloning reported in the cited art did not involve v-IL-6 like gene product. The applicant further argues that fig-1 does not include the complete viral genome and the V-IL-6 protein gene is one that is missing in the figure (response, page 2, para.4-5). The applicant further argues that viral gene product v-IL-6 has conserved 4 cysteine residues whereas the SEQ ID NO: 2 as disclosed in the cited art have only one cysteine residue. The applicant

Art Unit: 1636

further argues that the invention as claimed is drawn to an isolated nucleic acid molecule whereas the cited art teaches the expression of all genes within a lytic cycle, which requires a cell to be in-vivo, which is different from the expression of an isolated nucleic acid (as claimed). The applicant concluded that the cited art does describe the production of v-IL-6 like molecule from an isolated nucleic acid molecule.

However, this is not found persuasive because the cited art clearly teaches the identification of expressed viral genes in infected and uninfected cells (col. 8. line 64-67). The cited art teaches a cell line (BCBL-1, ATCC CRL 11982) encoding HHV-8 genomic DNA that is capable of producing HHV-8 viral particles (col.9, line 35-46). The cited art further teaches the detection of HHV-8 polypeptides in a biological sample using immunochemical assays (col.5, line 3-16, line 31-38). The scope of invention as claimed encompasses an isolated nucleic acid molecule which hybridizes the nucleic acid molecule of SEQ ID NO:1 and cell culture growth medium comprising recombinantly produced v-IL-6. If the composition is physically the same it must have the same properties. In instant case the cited art clearly anticipate the invention as claimed because the composition and functions as claimed are presumed inherent in this context. "Products of identical chemical composition can not have mutually exclusive properties." A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990) see MPEP § 2112.02. Therefore, the HHV-8 nucleic acid sequences as taught by Ganem would certainly hybridize with the nucleic acid of SEQ ID NO:1 as claimed and would inherently encodes v-IL-6 like activity. In addition, the cited art clearly anticipated the invention as claimed in claim 51, since the instant claim only requires a fragment (a single amino acid) of a polypeptide recombinantly obtained from DNA of HHV-8. Thus the invention as claimed has been clearly anticipated by the cited art of record.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 42 and 50 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 42 recites the limitation "the IL-6 receptor" in line 2. There is insufficient antecedent basis for this limitation in the claim.

Claim 42 recites the limitation "the receptor" in line 3. There is insufficient antecedent basis for this limitation in the claim.

Claim 50 recites the limitation "recombinantly produced IL-6" in line 1-2. There is insufficient antecedent basis for this limitation in the claim. Claim 50 depends upon claim 46, which is directed to an isolated nucleic acid.

Claim Objections

Claims 40, 41 and 44 are objected to because of the following informalities:

Claim 40 recite limitation "A fragment" -- The fragment -- is suggested.

Claim 41 recite limitation "A fragment" -- The fragment -- is suggested.

Claim 44 recite limitation "An isolated nucleic acid " -- The isolated nucleic acid -- is suggested.

Appropriate correction is required.

Conclusion

Claims 36-39, 43, 45, 47-49 and 52-53 are allowed

Claims 40, 41, 42, 44, 46, 50 and 51 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sumesh Kaushal Ph.D. whose telephone number is 703-305-6838. The examiner can normally be reached on Mon-Fri. from 9AM-5PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yucel Irem Ph.D. can be reached on 703-305-1998. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-8724 for After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

S. Kaushal
Patent examiner

Scott D. Pribe
SCOTT D. PRIEBE, PH.D.
PRIMARY EXAMINER